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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,352

07/07/2003

Peter M. Bonutti

782-A03-003-1

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33771 7590 01/15/2008
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SUITE 115
MIAMI, FL 33180

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

01/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/614,352	Applicant(s) BONUTTI, PETER M.	
	Examiner Diane Yabut	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8-21 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-21 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/2007 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 recites the limitation "said anchor" in lines 9-10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 8-11, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams** (U.S. Patent No. **6,099,552**) in view of **Schwartz** (U.S. Patent No. **6,306,159**).

Claims 1-3, 8-11, and 18-20: Adams discloses a cylindrical body portion **100** made of a metal (col. 2, lines 46-50) capable of use in soft tissue or bone defining a longitudinal central axis and including a first end and a second end, the second end including a pointed end portion **102** being conical in shape and operative to pierce body tissue and form an opening when a force is applied against a trailing end of the cylindrical body in a direction extending along the longitudinal central axis of the cylindrical body, and having a central axis which is coincident with the longitudinal central axis of the cylindrical body, and a plurality of passages **104** being substantially parallel each extending through the body portion orthogonal to the longitudinal central axis which allow for the threading of a suture, wherein a first passage is formed proximate said second conical end portion extending through the cylindrical body in a direction transverse to the longitudinal central axis of the cylindrical body, and a second passage extending through the cylindrical body substantially parallel to the first passage and disposed further from said conical end portion than said first passage of further from

said second end than said first passage or being located proximate mid-length of the cylindrical body (Figure 1).

Adams discloses the claimed device, except for first and second suture sections being passed through and extend away from said first and second passages, respectively, the suture threaded through said first passage and second passage being operative to rotate said anchor when first suture section is tensioned and the second suture section is relaxed, and a retainer connected to the suture for maintaining the tension in the suture.

Schwartz teaches first and second suture sections (two sections of **40**) being passed through and extending away from said first **24** and second **26** passages, respectively, the suture threaded through said first passage and said second passage, wherein the suture is operative to rotate an anchor **20** when first suture section is tensioned and the second suture section is relaxed, and a retainer connected to the suture for maintaining the tension in the suture (Figures 4-7; abstract, col. 2, lines 14-16). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Adams with Schwartz, in order to close a tissue defect, thereby promoting healing (col. 4, lines 11-13).

5. Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams** (U.S. Patent No. **6,099,552**) and **Schwartz** (U.S. Patent No. **6,306,159**), as applied to Claim 9 above.

Claims 12-17: Adams and Schwartz disclose the claimed device except for the cylindrical body being made of allogenic, autogenic, xenogenic, cortical bone, or a single piece of freeze dried bone, or made of a material selected from the group consisting of a metal, metal alloy, biodegradable material and bioerodible material, wherein the suture is secured relative to a body tissue being soft tissue or bone. It would have been obvious to one of ordinary skill in the art to use any of the above materials in either soft tissue or bone with the combined device of Adams and Schwartz, since it was known in the art that these materials are used with suture devices with soft tissue or bone.

6. Claims 21 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams** (U.S. Patent No. **6,099,552**) and **Schwartz** (U.S. Patent No. **6,306,159**), as applied to Claim 1 above, and further in view of **Ogiu** (U.S. Patent No. **4,235,238**).

Claims 21 and 26-27: Adams and Schwartz disclose the claimed device (see paragraph 4 above), except for having the first passage being formed to extend partially through the cylindrical body and partially through the pointed end portion.

Ogiu teaches a tissue-suturing apparatus with a passage used for threading suture that is formed partially in body portion 1 and partially in the pointed end portion portion 3 (Figure 51). It would have been obvious to one of ordinary skill in the art at the

time of invention to modify Adams and Schwartz by having one of the passages being formed partially in the body portion and partially in the pointed end portion, since Applicant has not disclosed that having the passage being formed partially in the body portion and partially in the pointed end portion solves any stated problem or is for any particular purpose and it appears that the device of Adams and Schwartz would perform equally well with a passage formed partially in the body portion and partially at its pointed end.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams** (U.S. Patent No. **6,099,552**) and **Schwartz** (U.S. Patent No. **6,306,159**), as applied to claim 1 above, and further in view of **Hayhurst** (U.S. Patent No. **4,741,330**).

Claim 24: Adams and Schwartz disclose the claimed device (see paragraph 4 above), except for a retainer having a first configuration in which the retainer is freely slidable along the suture and a second configuration in which the retainer is secured and connected to the suture for maintaining the tension in the suture.

Hayhurst teaches a retainer having a first configuration in which the retainer is freely slidable along the suture and a second configuration in which the retainer is secured and connected to the suture for maintaining the tension in the suture (see abstract, Figures 13-14, col. 8, lines 25-32). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a freely slidable retainer along the suture and being secured to the suture in order to maintain tension, as taught by

Hayhurst, to Adams and Schwartz in order to facilitate applying and maintaining tension to the sutures to properly promote tissue healing (col. 3, lines 29-35).

8. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams** (U.S. Patent No. **6,099,552**), **Schwartz** (U.S. Patent No. **6,306,159**), and **Hayhurst** (U.S. Patent No. **4,741,330**), as applied to claim 24 above, and further in view of **Egan** (U.S. Patent No. **6,106,545**).

Claim 25: Adams, Schwartz, and Hayhurst disclose the claimed device (see paragraphs 4 and 7), except for a retainer made of a material that becomes flowable when ultrasonic vibratory energy is applied.

Egan teaches a retainer **24** connected to a suture **22** that is made of a material that becomes flowable when ultrasonic vibratory energy is applied so that no knot is required to fix the suture in place (col. 3, lines 5-30). It would have been obvious to one of ordinary skill to provide a retainer that becomes flowable when ultrasonic vibratory energy is applied, as taught by Egan, to Adams, Schwartz, and Hayhurst since it was known in the art that retainers maintain tension in sutures and that retainers made of flowable material are beneficial in avoiding the challenging step of knotting the suture in place.

9. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams** (U.S. Patent No. **6,099,552**), **Schwartz** (U.S. Patent No. **6,306,159**), and **Hayhurst**

(U.S. Patent No. **4,741,330**), as applied to claim 24 above, and further in view of **Huxel** (U.S. Patent No. **6,503,259**).

Claim 28: Adams, Schwartz, and Hayhurst disclose the claimed device (see paragraphs 4 and 7), except for a force distribution member being disposed between the retainer and the body tissue.

Huxel teaches a force distribution member **16** being disposed between a retainer and body tissue (Figure 8). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a force distribution member, as taught by Huxel, to Adams, Schwartz, and Hayhurst in order to avoid over compression in one portion of tissue and to evenly distribute force on the surface of tissue (col. 4, lines 12-16).

Response to Arguments

10. Applicant's arguments filed 10/30/2007 have been fully considered but they are not persuasive.

11. Applicant argues that only after the anchor 20 is deployed by a push rod 86 and the flipping has already occurred is the tension applied to the suture to provide support against the outer rim wall 16 of the tissue, and not as a result of the suture being tensioned, as necessitated by the claims. The applicant also argues that by locating the hole of the outer wall anchor teaches away from the claimed invention. The examiner disagrees. Schwartz teaches "[w]ith tension on the suture, the outer wall anchor flips into place, providing support against the outer rim wall of the meniscus" (col. 2, lines 14-16). While the push rod 86 does deploy the anchor 20 out of the needle 80, and due to

gravity the anchor may flip, the applied tension on the suture still exerts torque on the anchor 20 – in other words it results in a force (that causes rotation) that keeps the anchor 20 supported against the tissue wall – and therefore Schwartz teaches this limitation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



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